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10/044,486	01/11/2002	Roger Y. Tsien	REGEN1510-1	9885

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,486

Applicant(s)

TSIEN ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 5-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been filed.

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DETAILED ACTION

Election/Restrictions

The restriction requirement presented previously is modified. The group set forth as Group I is divided as follows:

Group IA. Claims 1-3(part), 4, drawn to Compounds with A = S, classified in class 540, subclass 215, 222, 226, 227, 229.

Group IB. Claims 1-3(part), drawn to Compounds with A = O, classified in class 540, subclass 301.

Group IC. Claims 1-3(part), drawn to Compounds with A = CH₂, classified in class 540, subclass 205.

The inventions are distinct, each from the other because of the following reasons: Each of these groups represents a separate heterocyclic core, with the six membered ring being a thiazine, an oxazine and a pyrimidine respectively. These represent different categories of compounds: Cephalosporins, Oxacephems, and Carbacephems.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In view of the election of a cephalosporin specie, Group IA is deemed elected.

The election of species requirement set forth previously is withdrawn. That is, the entirety of Group IA has been searched.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The traverse of the previous restriction requirement is unpersuasive. Applicants argue a lack of burden. However, as set forth previously, Groups II and III have additional searches in Class 435, and the additional burden arises from that.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Quante.

See the species in patent claims 3-4, which correspond to R = thienylmethyl. The indole of claim 3, and the coumarin of claim 4 are taught by the reference to be fluorescent, and at any rate are extremely similar to the (III) and (IX) choices of claim 2 in this case.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The term "donor" is unclear. Donor of what? How would the claim be different if this word were removed? How does it limit Z?
2. The variable n is undefined in claim 1.
3. "General" is indefinite. A formula cannot be both general and specific. Deletion is suggested from claim 1.
4. Y as O in claim 2 is in error. Y is depicted in the structural formula as having 3 bonds; O forms only two bonds.
5. For R', what are "ester groups"? Esters are compounds, e.g. ethyl acetate. Do applicants intend moieties which with the rest of the molecule form an ester? If so, nearly all the choices in the claim are unnecessary (i.e. last 11 choices), since these form esters. Thus, it is unclear what is intended.
6. Choice (VI) in claim 2 is problematic. R3 is a linker variable and hence is divalent. However, this uses R3 also at the upper right in a monovalent role, which is impossible.
7. In (VII), does Me stand for metal or methyl? Either is conventional. For whichever choice is made, applicants must show that one of ordinary skill in the art would have known that this choice, and not another, was intended.
8. The term "ammonium cations" in claim 1 is unclear. Why is this in the plural – there should only be one. Further, is this just NH_4^+ , or is a substituted ammonium cation contemplated, and if so, substituted with what?

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9. The term "acyl" (in acyloxy and acylthio) is indefinite. Does this embrace acids of S?

P? As? What does the stem look like, i.e. if the acyl is e.g. RC(O), what is R?

10. The R' choice with "alpha" in it is garbled. Should the alpha appear first in the term, rather than in the middle?

11. The R3 definition in claim 2 is indefinite. The term "linker" does not convey what it is, only what the unknown group is attached to.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim 3 definition for n is new matter. No such definition appears in the specification.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim 2 definitions for X and Y are new matter. No such definitions appear in the specification.

Claims 2 and 3 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing

to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

The formula (V) is depicted in claim 2 as having three minus charges but no plus charge. A molecule without electrical neutrality is impossible to prepare and hence lacks enablement in terms of how to make, as such a thing cannot be made (paragraph 1). Note MPEP 2172.01: "A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP § 2164.08(c). Such essential matter may include missing elements ...". Here, the missing counterion is the missing element. On the other hand, if it was not the intention of applicants to claim such a non-neutral molecule, then the claim fails to set forth what applicants intend as their invention (paragraph 2). That is, it is not accurate because it is missing something. As stated in *In re Zletz*, 13 USPQ2d 1320, 1322, "An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous." Similarly in claim 3, one of the linkers has a plus charge but no balancing minus charge.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to teach how to use this compound. It does not fall within the ambit of Formula I, to which utility is tied. Compounds of Formula I have a CH₂ group attached to the cephalosporin, and to which Z is attached via a single bond. This

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species meets neither requirement. It has a CH group, not a CH₂ group, and Z is attached via a double bond, not a single bond. There being no other place in the specification which teaches the utility for this compound, it lacks an ascribed utility, and hence is not enabled.

Claim Objections

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim fails to limit claim 1 as it does not fall within claim 1 for reasons given in the previous paragraph.

Specification

Figure 7 is objected to, in that the text of the figure begins with a word in the lower case. Is there is a word missing, or is that supposed to be the first word of a sentence?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.

A handwritten signature in black ink, appearing to read "Mark Berch", with a stylized, cursive script.

Mark L. Berch
Primary Examiner
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July 8, 2003